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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/034,127	12/27/2001	Eric A. Holwitt	005274.P010	1617

7590 11/03/2003
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EXAMINER

HORLICK, KENNETH R

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 11/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/034,127	Applicant(s) HOLWITT ET AL.	
	Examiner Kenneth R Horlick	Art Unit 1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) 17-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 27 December 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
 If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
 * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
 a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>1 (4 pages)</u> | 6) <input type="checkbox"/> Other: _____ |

1. Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-16 and 22, drawn to methods for screening for biological sensors that bind to a selected analytes, and to biological sensors, classified in class 435, subclass 6, for example.
- II. Claims 17-21, drawn to methods of screening for products of biological reactions, classified in class 435, subclass 7.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different modes of operation and different functions. These represent different methods with different key steps and parameters; for example, Group I requires transformation of cells using an expression vector, and Group II requires preparing one or more recognition complexes.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and because the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

2. During a telephone conversation with Richard Nakashima on 08/26/03, a provisional election was made without traverse to prosecute the invention of Group I, claims 1-16 and 22. Affirmation of this election must be made by applicant in replying to this Office action. Claims 17-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

3. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

5. Claims 1-16 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-11 are confusing because while the preamble recites a method "of screening for biological sensors that bind to a selected analyte", it is not clear from the

recited steps a-e how this is accomplished. It is suggested that independent claim 1 be clarified so that the steps are in full agreement with the preamble.

B) Claims 12-16 and 22 are confusing because while claim 12 is drawn to “a biological sensor produced by the method of claim 1”, claim 1 is not drawn to a method of producing a biological sensor, but rather to a method of screening for biological sensors that bind to a selected analyte. Clarification is required.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 12-16 and 22 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These claims are product-by-process claims drawn to any and every possible biological sensor produced by the method of claim 1, although as noted above claim 1 is not actually drawn to a method of producing a biological sensor. Clearly, at the time of the invention the inventors were not in possession of such subject matter. In Technology Center 1600, such claims are referred to as “reach-through” claims, as protection is sought for any and every possible product which might possibly be made

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or identified by a given method. Surely there is no written descriptive basis for claims of this scope; further, there is no basis for a search of the prior art, as the claimed biological sensors (e.g. nucleic acids) are described merely by the method of making devoid of any physical or even functional properties.


7. Claims 1-16 and 22 are free of the prior art, but are rejected for other reasons. Claims 1-11 are drawn to a screening method for identifying biological sensors (e.g. nucleic acids) that bind to a selected analyte, comprising: preparing one or more candidate sensors; inserting each sensor into an expression vector comprising a target (i.e., reporter) gene, wherein the insertion site is located near the 5' end of the transcribed portion of the target gene; transforming the expression vectors into a host cell; exposing the host cells to the selected analyte; and identifying host cells that do not express the target gene protein. While the prior art teaches various assays involving expression of target or reporter genes linked to upstream controlling elements subject to binding by various nucleic acid-binding entities, no prior art has been found teaching or suggesting adapting such an expression system in the manner of the claims, so as to screen for nucleic acids which bind to a selected analyte. Chung (US 6,444,421), Kauffman et al. (US 6,100,035), and Edwards et al. (US 5,578,444) are made of record as references of interest.

8. No claims are allowable.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kenneth R Horlick whose telephone number is 703-308-3905. The examiner can normally be reached on Monday-Thursday 6:30AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 703-308-1119. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.


Kenneth R Horlick
Primary Examiner
Art Unit 1637

10/28/03